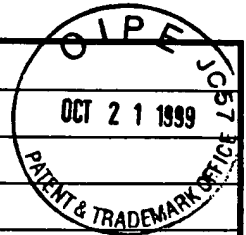


# TRANSMITTAL FORM

Application Serial Number	09/248,964
Filing Date	February 12, 1999
First Named Inventor	Wucherpennig et al.
Group Art Unit	1646
Examiner Name	Not yet assigned
Attorney Docket No.	HAR-005



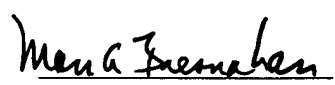
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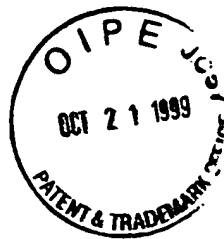
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| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Check Attached<br><input type="checkbox"/> Copy of Fee Transmittal Form<br><br><input type="checkbox"/> Amendment/Response<br><br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ____]<br><br><input type="checkbox"/> Extension of Time Request<br><br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input checked="" type="checkbox"/> Form PTO-1449<br><input checked="" type="checkbox"/> Copies of IDS Citations A1-A9, B1-B-9, C1-C77<br><br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><br><input type="checkbox"/> Response to Missing Parts/ Incomplete Application | <input type="checkbox"/> Copy of Notice to File Missing Parts of Application (PTO-1553)<br><br><input type="checkbox"/> Formal Drawing(s)<br><br><input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition to Convert to a Provisional Application<br><br><input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)<br><br><input type="checkbox"/> Terminal Disclaimer<br><br><input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application<br><br><input type="checkbox"/> Small Entity Statement<br><br><input type="checkbox"/> Request for Refund<br><br><input type="checkbox"/> After Allowance Communication to Group | <input type="checkbox"/> Appeal Communication to Board of Patent Appeals and Interferences<br><br><input type="checkbox"/> Appeal Communication to Group ( <i>Appeal Notice, Brief, Reply Brief</i> )<br><br><input type="checkbox"/> Status Letter<br><br><input checked="" type="checkbox"/> Return Receipt Postcard<br><input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8<br><br><input type="checkbox"/> Additional Enclosure(s) ( <i>please identify below</i> ) |
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 Date: October 14, 1999  
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GP 1646  
PATENT  
Attorney Docket No. HAR-005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Wucherpennig et al.

SERIAL NO.: 09/248,964

GROUP NO.:

1646

FILING DATE: February 12, 1999

EXAMINER:

Not yet assigned

TITLE:

MONOVALENT, MULTIVALENT, AND MULTIMERIC MHC  
BINDING DOMAIN FUSION PROTEINS AND CONJUGATES,  
AND USES THEREFOR

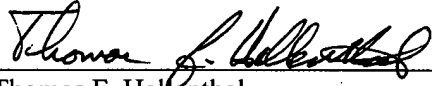
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CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231 on this 14<sup>th</sup> day of October, 1999.

  
Thomas F. Hellenthal

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith is/are:

Transmittal Form (1 pg.); Information Disclosure Statement (2 pgs.); PTO Form 1449 (7 pgs.); copies of references cited A1-A9, B1-B9, and C1-C77; and a return postcard.

BRESNAHA6615/8.A842071-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Wucherpennig et al.  
SERIAL NO.: 09/248,964 GROUP NO.: 1646  
FILING DATE: February 12, 1999 EXAMINER: Not yet assigned  
TITLE: MONOVALENT, MULTIVALENT, AND MULTIMERIC MHC  
BINDING DOMAIN FUSION PROTEINS AND CONJUGATES,  
AND USES THEREFOR



INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. §1.97, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the references are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **Filing Date** or before the mailing date of the **First Office Action** on the merits; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under Rule 1.17(p), namely **\$240.00**, is included herein, or
- ☐ (3) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, **AND**
- ☐ Applicant hereby Petitions the Commissioner to accept and consider the attached Information Disclosure Statement, **AND**



- ☐ the requisite Statement is below, AND
- ☐ the requisite petition fee due under Rule 1.17(i)(I), namely \$130.00 is included herein.

It is respectfully requested that each of the references shown on the attached Form PTO-1449 be made of record in this application.

### STATEMENT

As required under §1.97(e), Applicants, through the undersigned, hereby state either that [check the appropriate space]:

- ☐ 1. [E]ach item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application **not more than** three months prior to the filing date of the Information Disclosure Statement; or
- ☐ 2. [N]o item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any** individual designated in §1.56(c) **more than** three months prior to the filing of the Information Disclosure Statement.

### FEE AUTHORIZATION

Should any fee associated with the submission of this paper not be attached hereto as a check, the Commissioner is authorized to charge the missing fee to our Deposit Account, No. 20-0531. Any overpayments should be credited to said Deposit Account.

Respectfully submitted,

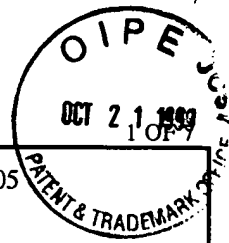
  
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BRESNAHA6615/8.842028



<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>	<b>ATTORNEY DOCKET NO.:</b> HAR-005 <b>APPLICANT(S):</b> Wucherpennig et al. <b>SERIAL NO.:</b> 09/248,964 <b>FILING DATE:</b> February 12, 1999 <b>GROUP:</b> 1646
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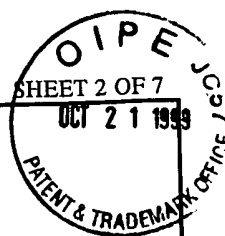
<b>U.S. PATENT DOCUMENTS</b>
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EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	5,928,647	07/27/99	Rock	424	196.11	01/10/94
	A2	5,820,866	10/13/98	Kappler et al.	424	192.1	03/04/94
	A3	5,714,166	02/03/98	Tomalia <i>et al.</i>	424	486	03/07/95
	A4	5,541,087	07/30/96	Lo et al.	435	697	09/14/94
	A5	5,338,532	08/16/94	Tomalia <i>et al.</i>	424	1.49	02/13/91
	A6	5,314,813	05/24/94	Peterson <i>et al.</i>	435	172.3	02/19/92
	A7	5,284,935	02/08/94	Clark <i>et al.</i>	530	403	12/28/90
	A8	5,260,422	11/09/93	Clark <i>et al.</i>	530	403	04/23/91
	A9	5,130,297	07/14/92	Sharma <i>et al.</i>	514	8	08/30/90

<b>FOREIGN PATENT DOCUMENTS</b>
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EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B1	WO 99/09064	02/25/99	PCT			11/04/97		Y
	B2	WO 98/06749	02/19/98	PCT			08/15/97		Y
	B3	WO 98/03552	01/29/98	PCT			07/15/97		Y
	B4	WO 97/44667	11/27/97	PCT			05/21/97		
	B5	WO 97/35991	10/02/97	PCT			03/28/97		Y
	B6	WO 96/04314	02/15/96	PCT			07/31/95		Y
	B7	WO 94/15635	07/21/94	PCT					
	B8	WO 93/10220	05/27/93	PCT			11/18/92		Y
	B9	0 393 707 A2	10/24/90	EP			04/20/90		Y

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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FORM PTO - 1449

INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: HAR-005

APPLICANT(S): Wucherpfennig et al.

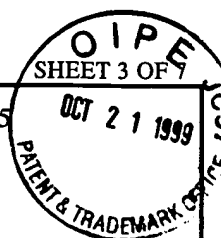
SERIAL NO.: 09/248,964

FILING DATE: February 12, 1999 GROUP: 1646

OTHER ART, JOURNAL ARTICLES, ETC.

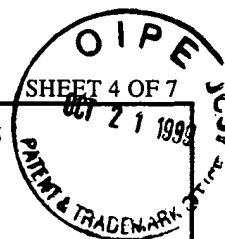
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C1	Altman <i>et al.</i> , "Phenotypic Analysis of Antigen-Specific T Lymphocytes" <i>Science</i> , 274:94-96 (1996)
	C2	Angel <i>et al.</i> , "Oncogene <i>jun</i> encodes a sequence-specific <i>trans</i> -activator similar to AP-1," <i>Nature</i> , 332:166-171 (1988)
	C3	Avva <i>et al.</i> , "In Vivo and In Vitro Formation and Dissociation of HLA-DR Complexes with Invariant Chain-Derived Peptides," <i>Immunity</i> , 1:763-774 (1994)
	C4	Bell, T.W., "Molecular Trees: A New Branch of Chemistry," <i>Science</i> , 271(5252):1077-8 (1996)
	C5	Bodmer <i>et al.</i> , "Nomenclature for factors of the HLA system, 1995," <i>Tissue Antigens</i> , 46:1-18 (1995)
	C6	Borman, S., "Technique gets peptides into living cells," <i>C&amp;EN</i> , 27-28 (July 10, 1995)
	C7	Bradley, D., "Dendrimers Display Liquid Crystal Talents," <i>Science</i> , 270:22 (1995)
	C8	Brake, A.J., Alpha-Factor Leader-Directed Secretion of Heterologous Proteins from Yeast," <i>Methods in Enzymology</i> , 185:408-421 (1990)
	C9	Brown <i>et al.</i> , "Three-dimensional structure of the human class II histocompatibility antigen HLA-DR1," <i>Nature</i> , 364:33-39 (1993)
	C10	Chan <i>et al.</i> , "Cloning and bacterial expression of a secreted soluble human MHC Class II beta-1 domain," <i>Biochemical Society Transactions</i> , 20:322S (1992)
	C11	Chang <i>et al.</i> , "A general method for facilitating heterodimeric pairing between two proteins: Application to expression of and T-cell receptor extracellular segments" <i>Proc. Natl. acad. Sci., USA</i> 91:11408-11412 (1994)
	C12	Chicz <i>et al.</i> , "Self-peptides bound to the type I diabetes associated class II MHC molecules HLA-DQ1 and HLA-DQ8," <i>International Immunology</i> , 6(11):1639-1649 (1994)
	C13	Chicz <i>et al.</i> , "Specificity and Promiscuity among Naturally Processed peptides Bound to HLA-DR Alleles," <i>J. Exp. Med.</i> , 178:27-47 (1993)
	C14	Claus <i>et al.</i> , "Are soluble monocyte-derived HLA class II molecules candidates for immunosuppressive activity?," <i>Immunology Letters</i> , 26(3):203-210 (1990)
EXAMINER		DATE CONSIDERED

<b>FORM PTO - 1449</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>	ATTORNEY DOCKET NO.: HAR-005
	APPLICANT(S): Wucherpfennig et al.
	SERIAL NO.: 09/248,964
	FILING DATE: February 12, 1999      GROUP: 1646



OTHER ART, JOURNAL ARTICLES, ETC.
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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C15	Collins <i>et al.</i> , "The three-dimensional structure of a class I major histocompatibility complex molecule missing the $\alpha 3$ domain of the heavy chain," <i>Proc. Natl. Acad. Sci. USA</i> , 92:1218-1221 (1995)
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	C18	Dagani, R., "Chemists Explore Potential of Dendritic Macromolecules as Functional Materials," <i>C&amp;EN</i> , 30-38 (June 3, 1996)
	C19	DeSimone, J.M., "Branching Out into New Polymer Markets," <i>Science</i> , 269:1060-1062 (1995)
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	C21	Fréchet, J.M.J., "Functional Polymers and Dendrimers: Reactivity, Molecular Architecture, and Interfacial Energy," <i>Science</i> , 263:1710-1715 (1994)
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	C23	Freemantle, M., "Potential Trigger for Dendrimer Switch," <i>C&amp;EN</i> , p. 30 (May 26, 1997)
	C24	Galliot, C., "Regioselective Stepwise Growth of Dendrimer Units in the Internal Voids of a Main Dendrimer," <i>Science</i> , 277:1981-1984 (1997)
	C25	Grégoire <i>et al.</i> , "Engineered secreted T-cell receptor $\alpha\beta$ heterodimers," <i>Proc. Natl. Acad. Sci. USA</i> , 88:8077-8081 (1991)
	C26	Hammer <i>et al.</i> , "Analysis of MHC Class II Peptide Interaction with M13 Peptide Display Libraries," <i>The Journal of Cellular Biochemistry</i> , Suppl. 17C, p. 215 (1993)
	C27	Hu <i>et al.</i> , "Sequence Requirements for Coiled-Coils: Analysis with $\lambda$ Repressor-GCN4 Leucine Zipper Fusions," <i>Science</i> , 250:1400-1403 (1990)
	C28	Hudson <i>et al.</i> , "Direct Visualization of Individual Cylindrical and Spherical Supramolecular Dendrimers," <i>Science</i> , 278:449-452 (1997)
EXAMINER		DATE CONSIDERED



FORM PTO - 1449  INFORMATION DISCLOSURE STATEMENT	ATTORNEY DOCKET NO.: HAR-005
	APPLICANT(S): Wucherpfennig et al.
	SERIAL NO.: 09/248,964
	FILING DATE: February 12, 1999      GROUP: 1646

**OTHER ART, JOURNAL ARTICLES, ETC.**

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C29	Jansen <i>et al.</i> , "Encapsulation of Guest Molecules into a Dendritic Box," <i>Science</i> , 266:1226-1230 (1994)
	C30	Jiang <i>et al.</i> , "Photoisomerization in dendrimers by harvesting of low-energy photons," <i>Nature</i> , 388(31):454-456 (1997)
	C31	Jones, E.V., "MHC class I and class II structures," <i>Curr. Opin. Immunol.</i> , 9(1):75-79 (1997)
	C32	Kalandadze <i>et al.</i> , "Expression of Recombinant HLA-DR2 Molecules," <i>The Journal of Biological Chemistry</i> , 271(33):20156-20162 (1996)
	C33	Kozono <i>et al.</i> , "Production of soluble MHC class II proteins with covalently bound single peptides," <i>Letters to Nature</i> , 369:151-154 (1994)
	C34	Kwok <i>et al.</i> , "Allele-Specific Motifs Characterize HLA-DLQ Interactions with a Diabetes-Associated Peptide Derived from Glutamic Acid Decarboxylase," <i>The Journal of Immunology</i> , 156(6):2171-2177 (1996)
	C35	Kwok <i>et al.</i> , "HLA-DQB1 Codon 57 is Critical for Peptide Binding and Recognition," <i>Journal of Experimental Medicine</i> , 183(3):1253-1258 (1996)
	C36	Heard, R., "HLA and autoimmune disease," <i>HLA and Disease</i> , 1994 Academic Press Ltd. pp. 123-151
	C37	Lin <i>et al.</i> , "Inhibition of Nuclear Translocation of Transcription Factor NF- $\kappa$ B by a Synthetic Peptide Containing a Cell Membrane-permeable Motif and Nuclear Localization Sequence," <i>The Journal of Biological Chemistry</i> , 270(24):14255-14258 (1995)
	C38	Madden, D.R., "The Three-Dimensional Structure of Peptide-MHC Complexes," <i>Annu. Rev. Immunol.</i> , 13:587-622 (1995)
	C39	Marsh <i>et al.</i> , "HLA Class II region nucleotide sequences, 1995," <i>Tissue Antigens</i> , 45:258-280 (1995)
	C40	Marsh, S.G.E., "Nomenclature for factors of the HLA system, update June 1995," <i>Tissue Antigens</i> , 46:142-143 (1995)
	C41	Mottershead <i>et al.</i> , "Direct Binding of the Mtv7 superantigen (Mls-1) to Soluble MHC Class II Molecules," <i>Immunity</i> , 2:149-154 (1995)
	C42	Nag <i>et al.</i> , "Functionally Active Recombinant and Chain-Peptide Complexes of Human Major Histocompatibility Class II Molecules" <i>The Journal of Biological Chemistry</i> , 271(17): 10413-10417 (1996)
EXAMINER		DATE CONSIDERED

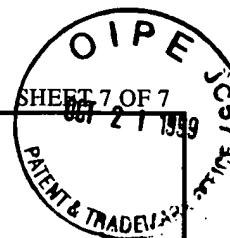




<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTORNEY DOCKET NO.:</b> HAR-005 <b>APPLICANT(S):</b> Wucherpfennig et al. <b>SERIAL NO.:</b> 09/248,964 <b>FILING DATE:</b> February 12, 1999 <b>GROUP:</b> 1646	
<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>			
<b>EXAM. INIT.</b>	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>		
	C43	Nag <i>et al.</i> , "In Vitro Maximum Binding of Antigenic Peptides to Murine MHC Class II Molecules does not Always Take Place at the Acidic pH of the In Vivo Endosomal Compartment," <i>The Journal of Immunology</i> , 148(2):369-372 (1992)	
	C44	Nicolle <i>et al.</i> , "Specific Tolerance to an Acetylcholine Receptor Epitope Induced in Vitro in Myasthenia Gravis CD4 <sup>+</sup> Lymphocytes by Soluble Major Histocompatibility Complex Class II-Peptide Complexes," <i>J. Clin. Invest.</i> , 93:1361-1369 (1994)	
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	C46	O'Shea <i>et al.</i> , "Preferential Heterodimer Formation by Isolated Leucine Zippers from Fos and Jun," <i>Science</i> , 245:646-648 (1989)	
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	C49	Roberts <i>et al.</i> , "Preliminary biological evaluation of polyamidoamine (PAMAM)Starburst™ dendrimers," <i>Journal of Biomedical Materials Research</i> , 30:53-65 (1996)	
	C50	Rolland <i>et al.</i> , "New Macromolecular Carriers for Drugs. I. Preparation and Characterization of Poly (oxyethylene- <i>b</i> -isoprene- <i>b</i> -oxyethylene) Block Copolymer Aggregates," <i>Journal of Applied Polymer Science</i> , 44:1195-1203 (1992)	
	C51	Scott <i>et al.</i> , "Role of Chain Pairing for the Production of Functional Soluble IA Major Histocompatibility Complex Class II Molecules," <i>J. Exp. Med.</i> , 183:2087-2095 (1996)	
	C52	Service, R.F., "Dendrimers: Dream Molecules Approach Real Applications," <i>Science</i> , 267:458-459 (1995)	
	C53	Sharma, S.D. <i>et al.</i> , "Antigen-Specific therapy of experimental allergic encephalomyelitis by soluble class II major histocompatibility complex-peptide complexes," <i>Proc. Natl. Acad. Sci. USA</i> , 88:11465-11469 (1991)	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

<b>FORM PTO - 1449</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>		ATTORNEY DOCKET NO.: HAR-005  APPLICANT(S): Wucherpfennig et al.  SERIAL NO.: 09/248,964  FILING DATE: February 12, 1999      GROUP: 1646	
OTHER ART, JOURNAL ARTICLES, ETC.			
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C54	Singh et al., "Starburst Dendrimers: Enhanced Performance and Flexibility for Immunoassays" Clin. Chem. 40/9, 1845-1849 (1994)	
	C55	Stern et al., "The Human class II MHC Protein HLA-DR1 Assembles as Empty $\alpha\beta$ Heterodimers in the absence of Antigenic Peptide," <i>Cell</i> , 68:465-477 (1992)	
	C56	Stinson, S.C., "Delving into Dendrimers," <i>C&amp;EN</i> , pp. 28-30, September 22, 1997	
	C57	Strominger et al., "The Class I and Class II Proteins of the Human Major Histocompatibility Complex," <i>JAMA</i> , 274(13):1074-1076 (1995)	
	C58	Shieh et al., "Erosion of a new family of biodegradable polyanhydrides," <i>Journal of Biomedical Materials Research</i> , 28:1465-1475 (1994)	
	C59	Tomalia, D.A., "Starburst/Cascade Dendrimers: Fundamental Building Blocks for a New Nanoscopic Chemistry Set," <i>Aldrichimica Acta</i> , 26(4):91-101 (1993)	
	C60	Tomalia et al., "Starburst Dendrimers: Molecular-Level Control of Size, Shape, Surface Chemistry, Topology, and Flexibility from Atoms to Macroscopic Matter," <i>Angew. Chem. Int. Ed. Engl.</i> , 29:138-175 (1990)	
	C61	Tomalia et al., "What promise for dendrimers?," <i>Nature</i> , 372:617-618 (1994)	
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<b>FORM PTO - 1449</b> <b>INFORMATION DISCLOSURE STATEMENT</b>		<b>ATTORNEY DOCKET NO.:</b> HAR-005 <b>APPLICANT(S):</b> Wucherpfennig et al. <b>SERIAL NO.:</b> 09/248,964 <b>FILING DATE:</b> February 12, 1999 <b>GROUP:</b> 1646	
<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>			
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